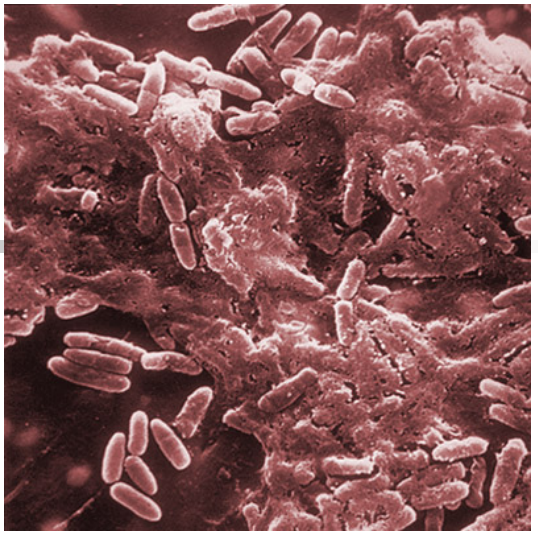
Endoscope Reprocessing Verification Testing



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Disclosures:

Sponsored to give invited presentations at various National and International conferences by;
STERIS, 3M, J&J, Healthmark, Ruhof, APIC, CACMID, Virox, Medisafe, Ontario Hospital Association, CHICA, and multiple conference associations.

The University of Manitoba has licensed Dr. Alfa's patent for Artificial Test Soil to Healthmark.

Opinion Leader Panel participation or Consulting Services for: 3M, J&J, STERIS, Serim, Karl Storz, Olympus, bioMerieux, Serim, Borden Ladner Gervais LLP, various Canadian Healthcare facilities.

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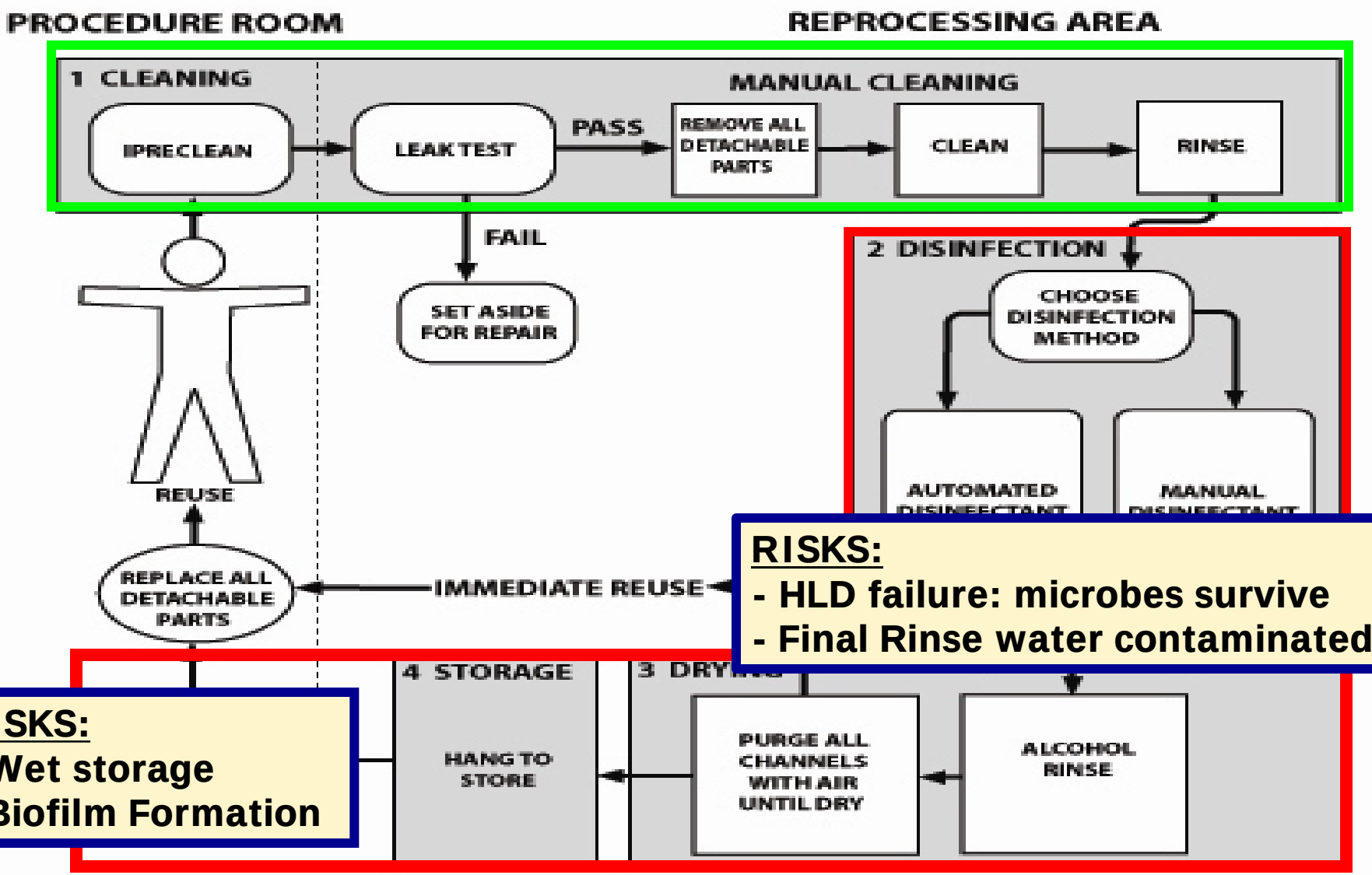
Objectives: Focus on Cleaning

- Verification (on site monitoring) testing at what stage in endoscope reprocessing?
- What verification tests are available?
- Published data
- Summary

Pictures from Google Images

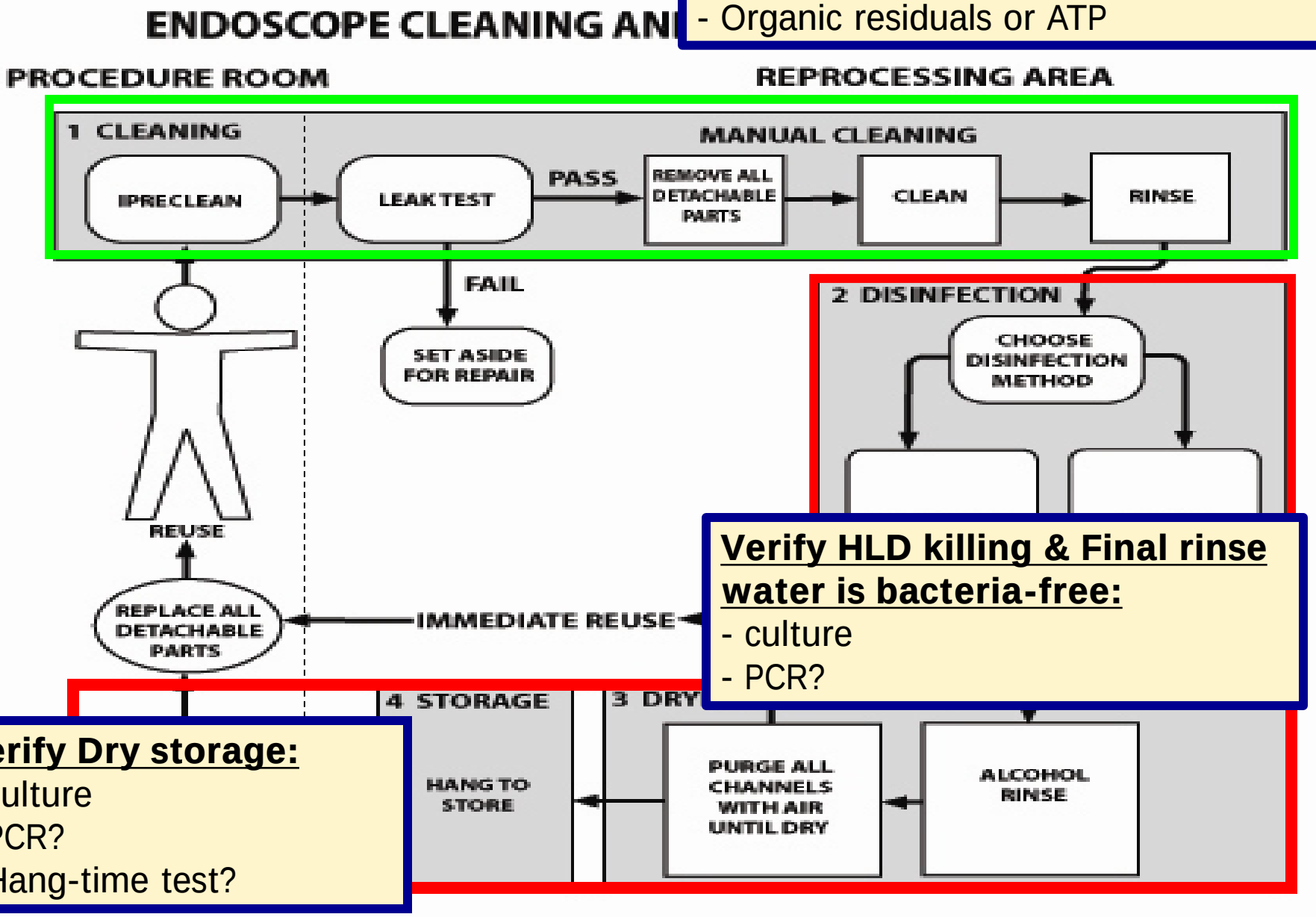
RISKS:
- inadequate manual cleaning



RISKS:
- HLD failure: microbes survive
- Final Rinse water contaminated

RISKS:
- Wet storage
- Biofilm Formation

Verify Manual Cleaning adequacy:
- Organic residuals or ATP

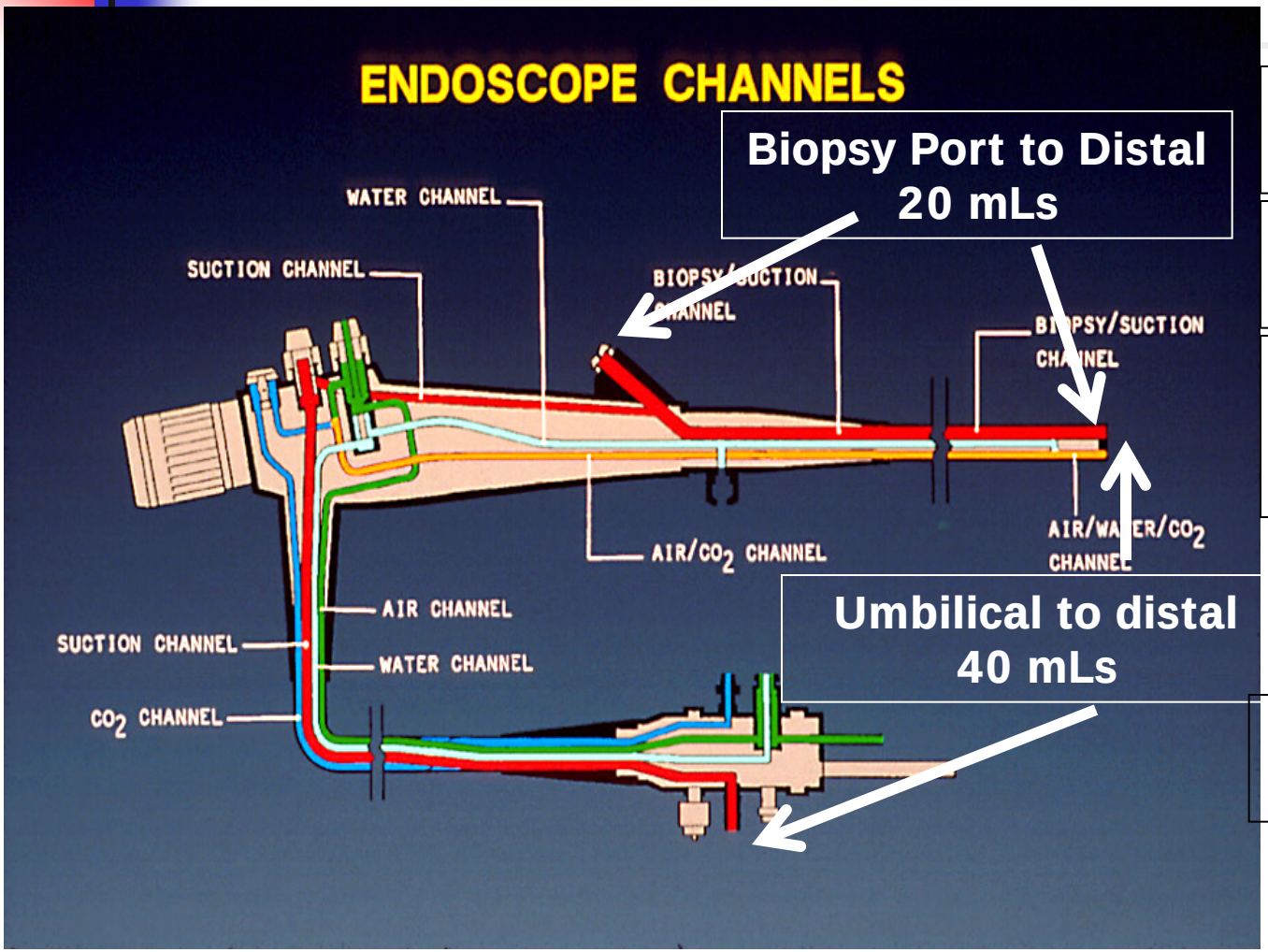


Verify HLD killing & Final rinse water is bacteria-free:
- culture
- PCR?

Verify Dry storage:
- culture
- PCR?
- Hang-time test?

Verification test:	When to do test:	What is it for:
Rapid organic tests: *[5mins]*	After manual cleaning	Has cleaning removed protein, carbohydrate, Hemoglobin (organics)
Rapid ATP tests: *[5 mins]*	After manual cleaning	Has cleaning removed organic material & microbes
Rapid Hang time test: *[15 mins]*	After storage	Detect residual Gram negative bacteria
Culture: *[24-48 hrs]*	After HLD or Storage	Type & level of viable bacteria
PCR: *[1-48 hrs]*	After HLD or Storage	What bacterial DNA remains?

What site(s) to sample for monitoring? What site(s) are most soiled?



1. Umbilical and Distal portions get soiled
2. Biopsy/suction channel most soiled
3. Biopsy port to distal section has ~80% of soil in entire channel

Duodenoscope lever ? sample collection

Figure from Olympus website

Alfa et al AJIC 1999 & 2014

What channels are most soiled post-bedside flush?

	Scope / channel N = 10 each	Bioburden Avg Log_{10}cfu / cm^2 [range]	Protein Avg ug / cm^2 [range]
Bowel prep	Colonoscope BP→distal	2.3 [0.9-2.9]	0.9 [0-5.2]
NO Bowel prep	Duodenoscope BP→distal	2.7 [1.4-5.0]	0.5 [0-2.0]
	Gastroscope BP→distal	2.6 [0.6-4.9]	2.6 [0-226]
	Alfa et al AJIC 2014		
	Duodenoscope EGW channel	1.69 [0-4.7]	0.20 [0-0.75]
	Alfa et al AJIC 2013		

Siimilar results found by: Pinneau L, DePhilippe E. Evaluation of endoscope cleanliness after reprocessing: a clinical-use study. Central Service 2013;1:23-27.

Manual Cleaning Benchmarks

- Manual flushing cutoffs (Alfa et al AJIC 1999):
  < 6.4 µg/cm^2 protein
  < 4 Log_{10} cfu/cm^2
- Pump flushing cutoffs (Alfa et al AJIC 2013):
  < 2 µg/cm^2 protein
  < 2 Log_{10} cfu/cm^2

Cutoffs confirmed and supported by L. Pinneau et al's study "Evaluation of endoscope cleanliness after reprocessing: A clinical-use study" Central Service 2013:1:22-27.

Rapid Manual Cleaning Monitors

Endoscope Channel Sample

Organic residuals

ATP: microbes & human secretions

Protein, Carb & Hg

glucose

protein

Detects: Carbohydrate, protein, hemoglobin (individually or together)

Detects ATP

This is not an exhaustive list: many different manufacturers

Pictures from company websites

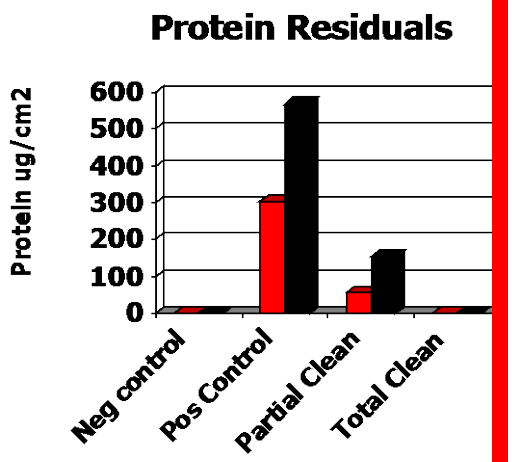
Monitoring tests need to be validated

- Not possible to validate by showing patient infection as an outcome
- Simulated-use to validate:
  - test will flag (+) if benchmark exceeded
  - sample collection method
- Clinical-use studies for intended application

Picture from free Google images

Simulated-use Evaluation

Duodenoscope: triplicate testing



Protein residuals:

- **Total clean: range 0.06 – 0.46 ug/cm²**
- **Partial clean: range 45 – 356 ug/cm²**

Bioburden residuals:

- **Total clean: range 2 – 3 Log_{10}/cm²**
- **Partial clean: range 5 – 6 Log_{10}/cm²**

ATP residuals:

- **Total clean: range 16 – 183 RLUs**
- **Partial clean: range 8,000 – 46,000 RLUs**

CLEAN Benchmarks:

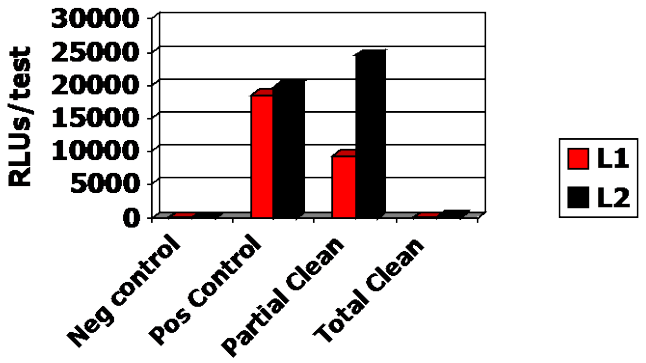
Protein: < 6.4 ug/cm²

Bioburden: < 4 Log_{10}/cm²

Sterile RO water to collect sample

L1: Suction/biopsy channel (40 mL)

L2: Air/water channel (20 mL)



Alfa et al AJIC 2013

Clinical Study: ATP to monitor manual cleaning of endoscope channels

Validated cut-off for adequate cleaning of: ≤ 200 RLUs
[entire length of channel was sampled – 40mLs]

Colonoscopes Post manual cleaning (N = 20):

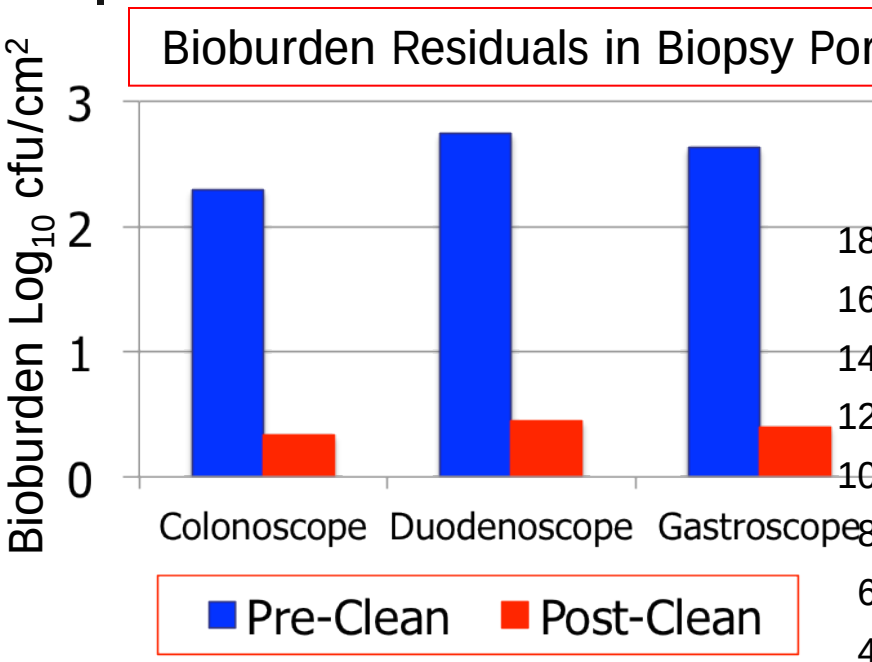
Suction/Biopsy channel:	100% clean: None > 200 RLUs
Air/Water channel:	100% clean: None > 200 RLUs
Auxillary water channel:	100% clean: None > 200 RLUs

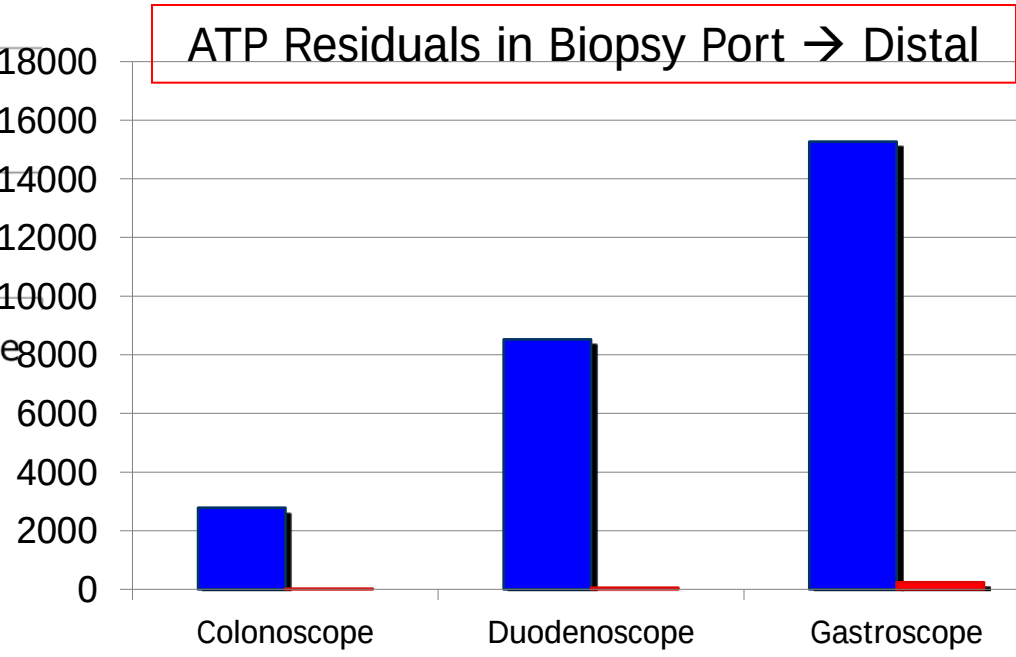
Duodenoscopes Post manual cleaning (N = 20):

Suction/Biopsy channel:	100% clean: None > 200 RLUs
Air/Water channel:	100% clean: None > 200 RLUs
Elevator GW channel:	75% clean: 25% > 200 RLUs (all < 700 RLUs)

Alfa M et al AJIC 2013

Clinical Study: Pump-assisted manual cleaning





Pre-Clean: N = 10
Post-Clean: N = 20
BP-distal: 20 mL sample

Alfa et al AJIC 2014

Pre-Clean Post-Clean

Pump-assisted Manual Cleaning of Patient-used GI scopes

Scope Type: BP → distal	**Bioburden** Average (range) Log_{10}/cm^2	**Protein** Average (range) $\mu g/cm^2$	**RLUs** Average (range)
Colonoscope: N = 20	**0.3** (0-1.6)	**0.1** (0-0.3)	**22.4** (11-54)
Duodenoscope: N = 20	**0.4** (0-1.6)	**0.2** (0-0.8)	**55.9** (22-135)
Gastroscope: N = 20	**0.4** (0-1.5)	**0.3** (0-1.0)	**239** (20-2350)*

* 4/20 samples exceeded 200 RLUs

Alfa et al AJIC 2014

Simulated-Use: Validation of Endoscope Channel Cleaning

Suction Channel:	ATP TEST 1	ATP TEST 2*
Cutoff for adequate clean:	< 200 RLUs	< 100 RLUs
Background ATP level:	≤ 20 RLUs	≤ 14 RLUs
Sample collection:	Flush channel	Sponge channel
Scale for Luminometer	0 to > 50,000 RLUs	0 to 9999 RLUs
Microbial residuals when clean: **[Target ≤ 4 Log_{10}/cm^2]**	≤ 2.5 Log_{10}/cm^2	≤ 2.0 Log_{10}/cm^2
Protein residuals when clean: **[Target ≤ 6.4 ug/cm^2]**	≤ 0.10 ug/cm^2 Alfa et al 2013	≤ 0.23 ug/cm^2 *Data not yet published

For Gram negative bacteria: Need > 20,000 cfu to get 200 RLU
ATP can NOT replace culture for detection of viable microbes

Organic Residual Prototype Test:

Canadian Multi-centre testing

- Prototype kits sent to 44 clinics from 23 Healthcare facilities;
  1499 scopes tested
- Sample: S/B → distal end using 10 ml sterile RO water

Alfa et al AJIC 2012;

Trans-Canada Survey of 44 sites: patient-used, cleaned GI scopes

N = 1499 scopes tested

	No:	Pos:	Carbohydrate	Protein	Blood
Gastroscope	**543**	**50 (9.2%)**	**0**	**3**	**47**
Colonoscope	**463**	**32 (6.9%)**	**5**	**2**	**25**
Bronchoscope	**251**	**10 (4%)**	**0**	**0**	**10**
Duodenoscope	**57**	**7 (12.3%)**	**0**	**0**	**7**
[EGW channel]	**21**	**4 (19.1%)**	**0**	**0**	**4**
Sigmoidoscope	**91**	**2 (2.2%)**	**0**	**0**	**2**

Alfa et al AJIC 2012

Stop Dirty Endoscopes at the Cleaning stage!!

- Once disinfected or sterilized residues are fixed → hard to extract and analyze
- Need to do routine monitoring of cleaning to ***prevent build up*** of fixed material on instruments.

Clipart from free google images, Endoscope picture courtesy Nancy Olson

Ofstead C et al Gastroenterology Nursing 2010 33:304-311

All 12 steps completed:
Manual cleaning & AER for HLD: 1.7%
Automated cleaning and HLD: 75.4%

Rapid *Cleaning* monitors will help detect errors up to this stage

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

Observed Activity	Steps Completed (%) (n = 69)
Leak test performed in clear water	77
Disassemble endoscope completely	100
Brush all endoscope channels and components	43
Immerse endoscope completely in detergent	99
Immerse components completely in detergent	99
Flush endoscope with detergent	99
Rinse endoscope with water	96
Purge endoscope with air	84
Load and complete automated cycle for high-level disinfection	100
Flush endoscope with alcohol	86
Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

Hang-Time test for Gram negative bacteria

- Manufacturer's information:
  - detects $\geq$100 cfu Gram negatives
- Test after storage → prior to use on patient
- Incubation of 10 mins
- No published validation or clinical data

When does risk of GI scope contamination increase?

- Risk increases with older scopes repeatedly used and reprocessed
  [Harder to clean & HLD]
- Culture (+) in 1.8% of 1376 gastroscopes and 1.9% of 987 colonoscopes [37% of isolates were Gram Neg]
  No neutralizer used
- PCR to detect biofilm [40% of culture (-) were PCR (+) for coliforms]

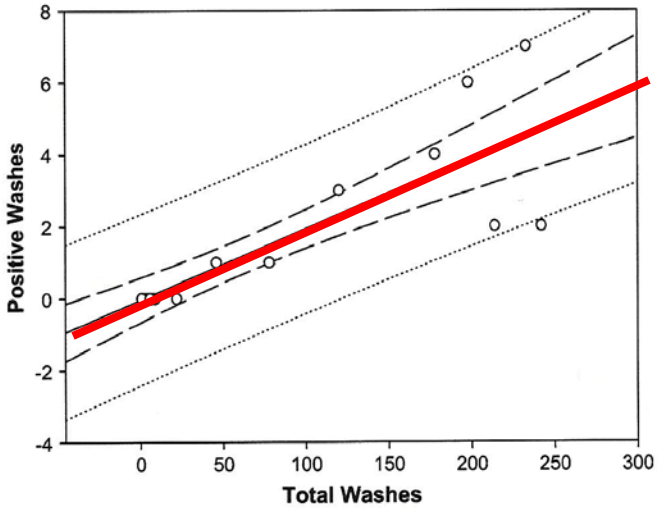


Fig 1. Linear regression analysis for gastroscopes, showing 99% and 95% confidence levels and prediction of contamination incidence numbers against total washes collected per gastroscope.

Bisset et al Am J Infect Control 2006;34:274-80

Culture monitoring all channels post-HLD

- ***Pinneau et al 2013: after HLD in AER***
  Neutralizer used:
  29/31 scopes (94%) culture (+)
  8/29 (28%) had bacteria of concern

- ***Alfa et al 2012: after weekend storage***
  No Neutralizer used:
  20/141 GI scopes (14%) culture (+)
  1/141 (0.7%) had bacteria of concern

Sampling ERCP Lever cavity

Table 1: Results of sampling[1] of elevator cavity of patient-used duodenoscopes, using the method previously developed by us

Sample Type[2]:	Duodenoscope number	Type of EGW channel	ATP (RLU)	Viable count (cfu/mL)[3]
sRO water	NA	NA	19	0
Baseline: fully reprocessed duodenoscopes tested after weekend storage				
Lever cavity	#43	sealed	45	0
Lever cavity	#44	sealed	53	0
Lever cavity	#45	sealed	47	0
Lever cavity	#25	un-sealed	21	0
Lever cavity	#27	un-sealed	26	0
Lever cavity	#28	un-sealed	71	0
Pre-clean (post bedside flush, before manual cleaning)				
Lever cavity	#43	sealed	250	9,300
Lever cavity	#44	sealed	3,246	28,000
Lever cavity	#45	sealed	2,888	4,800
Lever cavity	#25	un-sealed	442	60
Lever cavity	#25	un-sealed	7,698	1,270
Lever cavity	#28	un-sealed	2,992	20
Post-clean (post bedside flush, after manual cleaning)				
Lever cavity	#43	sealed	27	50
Lever cavity	#44	sealed	45	0
Lever cavity	#45	sealed	68	90
Lever cavity	#25	un-sealed	72	10
Lever cavity	#27	un-sealed	115	0
Lever cavity	#28	un-sealed	367	0

[1]The sampling method consisted of 1 mL sRO water flushed into the lever cavity, allowed to dwell for 1 minute and then flushed up/down 10 times.

[2] Each duodenoscope tested was from a separate patient-procedure

[3] A viable count of 0 cfu/mL indicates less than the limit of detection of 10 cfu/mL

Pictures courtesy of Nancy Olson

SUMMARY:

1. Rapid ATP and Organic tests:
   - validated for Cleaning monitoring
   - NOT validated for post-HLD testing
2. No Rapid tests available that can replace culture Post-HLD or Post-storage
3. Need Validation of sample collection for culture:
   - channels and ERCP lever cavity
   - need for neutralizer?
4. No testing methods for AER final rinse water
5. There is no test to confirm adequacy of drying

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Nancy Olson & Michelle Alfa

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